REMARKS

This paper is submitted in response to the final Office Action mailed on May 19, 2005. Because this amendment is submitted with a certificate of mailing in compliance with 37 C.F.R. §1.8 on or before the shortened statutory period for reply set to expire on August 19, 2005, this amendment is timely filed. Moreover, because this application is submitted within two (2) months of the mailing of the above-identified final Office Action, i.e., on or before **July 19, 2005**, Applicants are entitled to an Advisory Action issued prior to the expiration of the shortened statutory period for reply.[1]

I. STATUS OF AMENDMENT

Claims 18 to 33 are pending in this application with Claims 1 to 17 and 34 to 65 having been previously canceled without prejudice. By this response, none of the pending claims 18 to 33 are amended and no new claims have been added. Applicants submit that no additional claim or petition fees are required in connection with this application. However, please charge Deposition Account No. 02-1818 for any insufficiency of payment, excluding the issue fee, during the prosecution of this application.

II. CLAIM REJECTIONS

The Office Action rejects claims 18 to 33 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 3,780,308 (hereinafter "*Nablo*"). Applicants respectfully traverse the rejections of claims 18 to 33 as obvious over *Nablo* for at least the following reasons. In particular, claim 18 recites, in relevant part, a method for sterile filling a pre-sterilized container having a filling port with a bulk sterile fluid that includes introducing a filling port of a pre-sterilized container into the sterilizing field and transferring an aliquot of a bulk sterile fluid from a supply container to the pre-sterilized container through the filling port while in the a sterilizing field. In other words, the transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field, i.e., an area in which bacteria or other contaminants cannot survive.

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[1] Of course, Applicants acknowledge that should the Advisory Action be issued after the expiration of the three month shortened statutory period, extension fees will be calculated from the mailing date of the Advisory action.

Nablo does not, at any level, disclose or even suggest a device in which transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field. *Nablo* discloses an aseptic packaging system that includes a central pulser adapted to sequentially excite the sterilizing heads A, B, C positioned serially along the length of a conveyor 8. The sequentially operating sterilizing heads A, B and C correspond to the package 7, the filler spot 3' and package lid, respectively, Thus, when the head A is communicating an excitation field to the package 7, the filler spout 3' is **not** with the excitation field. Similarly, when the head B is communicating an excitation field to the filler spout 3' during the filling operation (see FIGS. 5a and 5b) the package 7 is **not** within the excitation field. Thus, because only one of the heads A, B and C is active and communicating an excitation field at any given time, it is impossible for both the package 7 and the filler spout 3' to be within the same excitation field such that the transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field as recited claim 18.

Moreover, Applicants respectfully traverse the allegation that tha high ozone level within the packaging region 4 is an active or controlled sterile field as recited by the claims at issue. Packaging region 4 is simply a region filled with a gas such as ozone or irradiated xenon in an effort to maintain the partial sterility of the packaging process once the package 7 travels out of the excitation fields established by head A. If, as the office action alleges, the presence of ozone or other gasses insure the sterility of the entire packaging region 4, then applicants are unclear as to why the excitation fields established by heads A, B and C are required? Much less, why are the complicated air purification and overpressure systems necessary? Surely it would be simpler and more cost effective to remove these systems and allow the gas to act as the sole sterilizing agent? Clearly, this is not the case and *Nablo* is merely hoping that the gas filled packaging region 4 maintains the sterility of the package 7 after leaving the excitation field established by the head A.

For all of these reasons, Applicants respectfully assert that claims 18 to 33 are not rendered obvious[2] by the teachings and disclosure of *Nablo*. Specifically, *Nablo* does not teach

[2]To establish a *prima facie* case of obviousness, three basic criteria must be met:

each and every element in the recited by the claims. As previously discusses, *Nablo* does not teach or even suggest a device in which transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field. Rather *Nablo* discloses sterilizing the package 7, moving the package 7 out of the excitation field and *then* filling the package 7 via a sterilized filler spout. The system of *Nablo* risks contamination because both elements are not in the excitation field simultaneously, and the gas within packaging region 4 does not establish an area in which bacteria or other contaminants cannot survive. Thus, the pending claims are patentable over any variation of modification of *Namblo*

III. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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Dated: July 19, 2005

(1) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

(2) Second, there must be a reasonable expectation of success.

(3) Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.